DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

July 13, 2004

**WARNING LETTER**
**CHI-17-04**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. Roy Luth, Owner
Roy and Gladice Luth Farm
25024 Rt. 173
Harvard, IL 60033

Dear Mr. Luth:

An investigation of your dairy farm operation conducted from March 23 and 24, 2004, found that a dairy cow from your establishment, was offered for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (Act).

On December 17, 2003, a dairy cow was sold for slaughter as human food to [redacted] The United States Department of Agriculture analysis of tissue samples collected from that animal identified the presence of 0.50 parts per million (ppm) penicillin in the kidney tissue. The established regulatory action level for penicillin in cattle is 0.05 ppm [Title 21, Code of Federal Regulations (21 CFR), Part 556.510]. The presence of this drug at the reported levels in the edible tissue from this animal causes the food to be adulterated under the Act.

Our investigation found that you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissue. The investigators found that you have no animal medication records that would identify which animal had been medicated, what type of medication had been used, and what the withdrawal time should be. You need to implement a system in which to record and maintain permanent drug treatment records to ensure that illegal tissue residues do not reoccur.

You also lack an adequate inventory system for determining the quantities of drugs used to medicate your cows. An accurate drug inventory assures that medications used to treat animals are not being misused and serves as additional assurance that animal treatment records reflect actual dosages administered.

You are also adulterating the veterinary drug Pen-Aquous penicillin G procaine (penicillin) that your firm uses on cows when you fail to use in conformance with its approved labeling. In this case, the proper withdrawal time was not observed per 21 CFR Part 522.1696b. Failure to observe appropriate withdrawal times makes the drug unsafe within the meaning of Section 512(a) and adulterated under Section 501(a)(5).

1. The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law To avoid future illegal residue violations you should take precautions such as: Implementing a system to identify which animals have been medicated and with what drug(s); and

2. If an animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate amount of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food and should be clearly identified and sold as a medicated animal.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. This action may include, but is not limited to, obtaining a court injunction against you directly or indirectly offering livestock for slaughter for food.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you receive this letter what steps you are taking to correct the problem. Your response should include each step that has been taken or will be taken to correct prevent these problems from happening again. If you need more time, let us know the reason for the delay and when you expect to complete your correction. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Director, Compliance Branch, at the above address. If you have any questions about the contents of this letter, please call Mr. Harrison at (312) 596-4220.

Sincerely,

Scott J. MacIntire
District Director